# *2011 DRAFTING REQUEST*

## Bill

Received: **10/04/2011**

Received By: **tdodge**

Wanted: **As time permits**

Companion to LRB:

For: **Peggy Krusick (608) 266-1733**

By/Representing: **Mary Matthias**

May Contact: **Mary Matthias - Leg. Council**

Drafter: **fknepp**

Subject: **Health - miscellaneous**

Addl. Drafters:

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Krusick@legis.wisconsin.gov**

Carbon copy (CC:) to: **Mary.Matthias@legis.wisconsin.gov**
**Fern.Knepp@legis.wisconsin.gov**
**tamara.dodge@legis.wisconsin.gov**

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**Pre Topic:**

No specific pre topic given

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**Topic:**

Require prescribers to notify about off label use of and financial interest in drugs and medical devices

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**Instructions:**

See attached

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**Drafting History:**

| Vers. | Drafted | Reviewed | Typed | Proofed | Submitted | Jacketed | Required |
|---|---|---|---|---|---|---|---|
| /? | tdodge<br>11/14/2011 | | | _____<br>_____ | | | |
| /P1 | fknepp<br>12/09/2011<br>fknepp<br>02/23/2012 | scalvin<br>01/05/2012<br>scalvin<br>01/09/2012<br>scalvin<br>03/07/2012 | rschluet<br>01/09/2012 | _____<br>_____<br>_____<br>_____<br>_____<br>_____ | mbarman<br>01/09/2012 | | |

| Vers. | Drafted | Reviewed | Typed | Proofed | Submitted | Jacketed | Required |
|---|---|---|---|---|---|---|---|
| /P2 | | | jmurphy<br>03/07/2012 | _____<br>_____ | mbarman<br>03/07/2012 | | Crime |
| /1 | fknepp<br>03/08/2012 | csicilia<br>03/09/2012 | rschluet<br>03/09/2012 | _____<br>_____ | sbasford<br>03/09/2012 | mbarman<br>03/09/2012 | |

FE Sent For:

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| /P2 | | 1 cjs 3/9 12 | jmurphy 03/07/2012 | | mbarman 03/07/2012 | | |

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| /P2 | | 3/1/12 SMC + cjs<br>3/6/12 | jm<br>3/7 | RS & PH<br>3/7 | | | |

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|---|---|---|---|---|---|---|---|
| /? | tdodge | /P1 01/03/11 sac | 1 gs 1/9/12 | | | | |

FE Sent For:

**<END>**

**Dodge, Tamara**

**From:** Matthias, Mary
**Sent:** Monday, October 03, 2011 11:37 AM
**To:** Dodge, Tamara
**Cc:** Johnson, Rachel
**Subject:** drafting request-medical practice

Good morning-

I am not sure if you're the correct person for this draft- if not, could you forward it to the correct drafter? Thanks.

Rep. Krusick would like a draft requiring prescribers to notify patients about "off-label" uses of drugs and medical devices AND to inform patients about any financial interest a physician may have in a drug or device they prescribe or use.

According to Wikipedia: **Off-label use** is the practice of prescribing pharmaceuticals for an unapproved indication or in an unapproved age group, unapproved dose or unapproved form of administration

It isn't necessary to use the term "off-label" anywhere in the draft.

The draft should provide all of the following:

1. If a physician (or other prescriber) prescribes a drug for an "off-label" use, the prescriber must notify the patient that the prescribed use is "off-label" and obtain the patient's signature attesting that they have received the information. This can be a one-time notification (provided the first time the prescriber prescribes the drug for a particular patient). The doctor should maintain the record—do you have nay thoughts on what would be a reasonable amount of time for maintenance of the record?

2. If a physician intends to use a device or drug in the course of treating a patient (such as installing a device in a patient's body or using a drug during surgery) and the use of the device or drug is "off-label", the physician must provide written information explaining that the use is "off-label" and what that means, and must obtain the patient's signature attesting that they have received the information.

3. Require DHS to prepare the written information that prescribers must hand out to patients for items 1 and 2 above. The written information must explain what "off-label" use is.

Here's a draft from 2001 that is analogous and might be helpful in drafting items 1-3 (there are extraneous things in the 2001 draft that Rep. Krusick doesn't need in this draft, such as explanation of alternatives, statement about military service, etc.)

https://docs.legis.wisconsin.gov/2001/related/proposals/ab672.pdf

State of Wisconsin
2001 - 2002 LEGISLATURE

LRB-3587/1
MDK:cjs:rs

# 2001 ASSEMBLY BILL 672

December 7, 2001 - Introduced by JOINT LEGISLATIVE COUNCIL. Referred to Committee on Health.

AN ACT ***to amend*** 448.02 (3) (a); and ***to create*** 115.357 and 448.35 of the statutes; **relating to:** requiring physicians to provide certain information when issuing prescription orders to treat children with attention deficit hyperactivity disorder.

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***Analysis by the Legislative Reference Bureau***

For further information see the ***state*** fiscal estimate, which will be printed as an appendix to this bill.

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***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

PREFATORY NOTE: This bill was prepared for the joint legislative council's special committee on use of prescription drugs for children.

***REQUIREMENT FOR A PHYSICIAN ISSUING A PRESCRIPTION ORDER FOR A CHILD FOR TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER TO PROVIDE CERTAIN INFORMATION***

***Treatment of Attention Deficit Hyperactivity Disorder With a Prescription Drug***

The bill requires any physician who diagnoses a child (any person less than 18 years old) with attention deficit hyperactivity disorder (ADHD) and issues a prescription order for treatment of the disorder to provide certain information to the parent or guardian of the child or to an adult who is with the child at the time the prescription order is issued, if any. If the child is 14 years of age or older, the physician must also provide the information to the child.

If a physician treats a child for ADHD with a prescription drug on a long-term basis, the physician must provide the information when issuing the initial prescription order and at least once every 2 years thereafter. A physician is not required to provide the information in an emergency or if the physician reasonably believes that another physician has issued a prescription order for the child for the same prescription drug within the past year.

Under the circumstances described above, a physician must provide all of the following information:

1. An explanation of the method of diagnosis used, including the results of any tests or evaluations.

2. Information on alternative modes of treatment, as provided in s. 448.30, stats., which provides as follows:

"**448.30 Information on alternate modes of treatment.** Any physician who treats a patient shall inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician's duty to inform the patient under this section does not require disclosure of:

(1) Information beyond what a reasonably well-qualified physician in a similar medical classification would know.

(2) Detailed technical information that in all probability a patient would not understand.

(3) Risks apparent or known to the patient.

(4) Extremely remote possibilities that might falsely or detrimentally alarm the patient.

(5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.

(6) Information in cases where the patient is incapable of consenting.".

3. A printed copy of the informational materials pertaining to the assessment and treatment of ADHD prepared by the department of health and family services (DHFS). The requirement for DHFS to prepare those materials is described below.

***Treatment of ADHD With a Schedule II Controlled Substance***

In addition to providing the materials described above, a physician who diagnoses a child with ADHD and prescribes a Schedule II controlled substance for treatment of the disorder must provide a printed copy of any materials pertaining to the substance which have been prepared by DHFS.

A physician who is required to provide any of the information (as described above) must obtain certification in writing from the parent or guardian of the child or the adult to whom the information is provided, if any, that the physician has provided all of the required information.

***Penalty for Failure to Provide Information; Exemption***

Under current law, a physician who, after investigation and a hearing, is found guilty of unprofessional conduct is subject to disciplinary action by the medical examining board. The bill provides that an allegation that a physician has failed to provide the required information or obtain the required certification is an allegation of unprofessional conduct. However, the bill provides that it is not unprofessional conduct for a physician to fail to provide the informational materials prepared by DHFS, if the physician made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make materials available at the time the physician was required to provide them.

***PREPARATION OF INFORMATIONAL MATERIALS BY DHFS***

***Materials Pertaining to the Assessment and Treatment of ADHD***

The bill requires DHFS to prepare informational materials on the assessment and treatment of ADHD. These are the materials which must be provided by a physician who prescribes any prescription drug for the treatment of ADHD in a child. The materials must contain the following:

1. A summary of the practice parameters for the assessment and treatment of children and adolescents with ADHD published by the American Academy of Child and Adolescent Psychiatry.

2. A statement that a parent or guardian may seek treatment other than prescription drugs for a child with ADHD.

***Materials Pertaining to Schedule II Controlled Substances***

In addition to the materials above, the bill requires DHFS to prepare informational materials on certain Schedule II controlled substances. These are the additional materials that must be provided by a physician who prescribes any Schedule II controlled substance for treatment of ADHD in a child. DHFS must, in consultation with the State Medical Society of Wisconsin, determine which Schedule II controlled substances are routinely prescribed by physicians in this state to treat ADHD in children. For each of these substances, DHFS must prepare materials containing the following information:

1. A statement that the substance is a Schedule II controlled substance under s. 961.16.

2. A summary of information included in the labeling of the substance required by federal law pertaining to the safety and effectiveness of the substance when used to treat ADHD in children, including any information relating to the potential for abuse or development of dependence upon the drug.

3. A statement that use of a the Schedule II controlled substance to treat ADHD may affect a person's eligibility to serve in the U.S. armed forces, if the DHFS so finds.

4. A statement that the use of a Schedule II controlled substance to treat ADHD may affect the cost of a person's health insurance.

DHFS must prepare all of the informational materials within approximately 5 months after the effective date of the bill. Physicians are first required to provide the required information beginning approximately 9 months after the effective date of the bill.

***Dissemination of Materials by the Department of Public Instruction***

The bill requires the department of public instruction (DPI) to disseminate the informational materials prepared by DHFS to appropriate public school staff.

**SECTION 1.** 115.357 of the statutes is created to read:

**115.357 Information on attention deficit hyperactivity disorder.** The department shall disseminate to appropriate public school staff the information regarding the diagnosis and treatment of attention deficit hyperactivity disorder and prescription drugs used to treat the disorder prepared by the department of health and family services under s. 448.35 (2).

NOTE: Requires the DPI to distribute the informational materials prepared by DHFS to appropriate public school staff.

**SECTION 2.** 448.02 (3) (a) of the statutes is amended to read:



448.02 **(3)** (a) The board shall investigate allegations of unprofessional conduct and negligence in treatment by persons holding a license, certificate or limited permit granted by the board. An allegation that a physician has violated s. 253.10 (3), 448.30, 448.35 (3), or 450.13 (2) or has failed to mail or present a medical certification required under s. 69.18 (2) within 21 days after the pronouncement of death of the person who is the subject of the required certificate or that a physician has failed at least 6 times within a 6-month period to mail or present a medical certificate required under s. 69.18 (2) within 6 days after the pronouncement of death of the person who is the subject of the required certificate is an allegation of unprofessional conduct. Information contained in reports filed with the board under s. 49.45 (2) (a) 12r., 50.36 (3) (b), 609.17 or 632.715, or under 42 CFR 1001.2005, shall be investigated by the board. Information contained in a report filed with the board under s. 655.045 (1), as created by 1985 Wisconsin Act 29, which is not a finding of negligence or in a report filed with the board under s. 50.36 (3) (c) may, within the discretion of the board, be used as the basis of an investigation of a person named in the report. The board may require a person holding a license, certificate or limited permit to undergo and may consider the results of one or more physical, mental or professional competency examinations if the board believes that the results of any such examinations may be useful to the board in conducting its investigation.

NOTE: Amends the statute which authorizes the medical examining board to investigate allegations of unprofessional conduct and impose penalties against a physician who is found guilty of unprofessional conduct. Specifically, provides that an allegation that a physician violated s. 448.35 (3), stats., requiring physicians to provide certain informational materials, as created in SECTION 3 of the bill, is an allegation of unprofessional conduct. SECTION 3 of the bill also creates an exemption which provides that a physician is not guilty of unprofessional conduct for failure to provide the informational materials prepared by DHFS if the physician made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make the materials available.

**SECTION 3.** 448.35 of the statutes is created to read:

**448.35 Attention deficit hyperactivity disorder. (1)** DEFINITIONS. In this section:

(a) "Child" means a person under 18 years of age.

(b) "Department" means the department of health and family services.

(c) "Prescription drug" has the meaning given in s. 450.01 (20).

(d) "Prescription order" has the meaning given in s. 450.01 (21).

(e) "Schedule II controlled substance" means any substance included under s. 961.16.

**(2)** INFORMATIONAL MATERIALS. (a) The department shall prepare informational materials which contain the following:

1. A summary of the practice parameters for the assessment and treatment of children and adolescents with attention deficit hyperactivity disorder published by the American Academy of Child and Adolescent Psychiatry.

2. A statement that a parent or guardian may seek treatment other than prescription drugs for a child with attention deficit hyperactivity disorder.

(b) The department shall, in consultation with the State Medical Society of Wisconsin, determine which Schedule II controlled substances are commonly prescribed by physicians in this state to treat attention deficit hyperactivity disorder and shall prepare informational materials pertaining to each of those substances containing the following information:

1. A statement that the substance is a Schedule II controlled substance.

2. A summary of the information included in the labeling of the substance under 21 USC 352 (f) which relates to the safety and effectiveness of the substance when used to treat attention deficit hyperactivity disorder in children and the potential for abuse or development of dependence upon the substance.



3. A statement that use of the substance to treat attention deficit hyperactivity disorder may affect a person's eligibility to serve in the U.S. armed forces, if the department so finds.

4. A statement that a person's use of the substance to treat attention deficit hyperactivity disorder may affect the cost of health insurance for that person.

(c) The materials prepared under pars. (a) and (b) shall be made available to physicians and to the public on the department's internet site. Upon the request of a physician, the materials under pars. (a) and (b) shall be provided to the physician in printed form.

(d) The materials under pars. (a) and (b) shall be made available to physicians and to the public no later than the first day of the 6th month beginning after the effective date of this paragraph .... [revisor inserts date].

(e) The department shall periodically review the materials under pars. (a) and (b) and shall exercise reasonable diligence in providing materials that are accurate and current.

**(3)** REQUIREMENTS FOR PHYSICIANS. (a) Except in an emergency and as provided under par. (e), a physician who diagnoses a child with attention deficit hyperactivity disorder and issues a prescription order for treatment of the disorder shall provide the following information to the persons specified in par. (c):

1. An explanation of the method of diagnosis used, including the results of any tests or evaluations.

2. Information on alternative modes of treatment, as provided in s. 448.30.

3. A printed copy of the materials prepared under sub. (2) (a).

(b) In addition to the information required under par. (a), except in an emergency and as provided under par. (e), a physician who diagnoses a child with

attention deficit hyperactivity disorder and issues a prescription order for a Schedule II controlled substance for treatment of the disorder shall provide a printed copy of any materials pertaining to the prescribed substance which have been prepared by the department under sub. (2) (b) to the persons specified in par. (c).

(c) A physician required to provide information under this section shall provide the information to the parent or guardian of the child if the parent or guardian of the child is present when the prescription order is issued. If the child is 14 years of age or older, the physician shall also provide the information to the child. If the child's parent or guardian is not present at the time the prescription order is issued, the physician shall provide the information to an adult who is with the child at the time the prescription order is issued, if any.

(d) A physician shall obtain from the parent or guardian of the child, or the adult to whom the information is provided, if any, certification in writing that the physician has provided the information required under this section.

(e) A physician who treats a child for attention deficit hyperactivity disorder on a long-term basis with the same prescription drug shall provide the information and obtain the certification required under this section when issuing the initial prescription order for that prescription drug and at least once every 2 years thereafter. A physician is not required to provide the information described under sub. (2) if the physician reasonably believes that another physician has issued a prescription order for the child for the same prescription drug within the past year.

**(4)** EXEMPTION. It is not unprofessional conduct under s. 448.02 (3) (a) for a physician to fail to provide the materials required under this section if the physician made a reasonably diligent effort to obtain the materials from the department and



the department did not make the materials available at the time that the physician was required to provide them.

NOTE: Creates the requirements for physicians to provide certain information when issuing a prescription order to treat ADHD in a child, and for DHFS to prepare those informational materials, as described above in the prefatory note.

Also creates an exemption to an allegation of unprofessional conduct as described in the note following SECTION 2.

**SECTION 4. Initial applicability.**

(1) The treatment of sections 448.02 (3) (a) and 448.35 (3) of the statutes first applies to prescription orders that are issued on the first day of the 10th month beginning after the effective date of this subsection.

NOTE: Provides that the requirements pertaining to physicians do not take effect until the first day of the 10th month after the effective date of the bill.

**(END)**

## Dodge, Tamara

**From:** Matthias, Mary
**Sent:** Tuesday, October 04, 2011 9:43 AM
**To:** Dodge, Tamara
**Cc:** Johnson, Rachel
**Subject:** RE: drafting request-medical practice

I would like to see it.

Thanks!

*Mary Matthias*
Senior Staff Attorney
Wisconsin Legislative Council Staff
Ph.(608)266-0932;Fax (608)266-3830

---

**From:** Dodge, Tamara
**Sent:** Tuesday, October 04, 2011 9:42 AM
**To:** Matthias, Mary
**Subject:** RE: drafting request-medical practice

Mary,

I will be handling this draft. Would you like to receive copies of this draft? Or should I just communicate solely with Rep. Krusick's office?

Tami

**Tamara J. Dodge**
Attorney
Wisconsin Legislative Reference Bureau
P.O. Box 2037
Madison, WI 53701-2037
(608) 267 - 7380
tamara.dodge@legis.wisconsin.gov

---

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**Sent:** Monday, October 03, 2011 11:37 AM
**To:** Dodge, Tamara
**Cc:** Johnson, Rachel
**Subject:** drafting request-medical practice

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Rep. Krusick would like a draft requiring prescribers to notify patients about "off-label" uses of drugs and medical devices AND to inform patients about any financial interest a physician may have in a drug or device they prescribe or use.

According to Wikipedia: **Off-label use** is the practice of prescribing pharmaceuticals for an unapproved indication or in an unapproved age group, unapproved dose or unapproved form of administration

It isn't necessary to use the term "off-label" anywhere in the draft.

The draft should provide all of the following:

1. If a physician (or other prescriber) prescribes a drug for an "off-label" use, the prescriber must notify the patient that the prescribed use is "off-label" and obtain the patient's signature attesting that they have received the information. This can be a one-time notification (provided the first time the prescriber prescribes the drug for a particular patient). The doctor should maintain the record—do you have nay thoughts on what would be a reasonable amount of time for maintenance of the record?

2. If a physician intends to use a device or drug in the course of treating a patient (such as installing a device in a patient's body or using a drug during surgery) and the use of the device or drug is "off-label", the physician must provide written information explaining that the use is "off-label" and what that means, and must obtain the patient's signature attesting that they have received the information.

3. Require DHS to prepare the written information that prescribers must hand out to patients for items 1 and 2 above. The written information must explain what "off-label" use is.

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https://docs.legis.wisconsin.gov/2001/related/proposals/ab672.pdf

4. Require a physician to disclose to a patient if the prescriber has any conflict of interest in a drug, device or other product they are prescribing to a patient or intend to use in treating the patient that is not directly prescribed to the patient (such as a device or drug used during surgery). I don't think you necessarily have to use the term conflict of interest. The general idea is that if the physician has any sort of financial interest in the drug or device-or the company producing the drug or device- or is going to get a kickback--anything other that what is "usual and customary" for a physician to receive for prescribing or using a drug or device—then they have to inform the patient of the nature of the relationship that they have with the company. Require the physician to obtain and maintain written verification that they have made the disclosure to the patient.

Thanks--

Mary

*Mary Matthias*
Senior Staff Attorney

Wisconsin Legislative Council Staff
Ph.(608)266-0932;Fax (608)266-3830

## Dodge, Tamara

**From:** Dodge, Tamara
**Sent:** Thursday, October 13, 2011 4:39 PM
**To:** Matthias, Mary
**Cc:** Johnson, Rachel
**Subject:** RE: drafting request-medical practice

Mary,

I'm have some questions about this drafting request.

First, to answer your question: The signed attestation about receiving information about off-label use should probably be included in the patient's medical record and then the time for keeping that would be tied to the time the medical record is maintained. If you are referring to the time the attestation should be renewed for the same use of the same drug, last year's psychotropic drug section (s. 50.08) provides that the consent is value for not longer than 15 months. The ADHD draft uses 2 years. Either of those seem reasonable.

What exactly is DHS supposed to create with regard to off-label use? In the example draft, DHS could create information sheets because it was dealing with one disorder (ADHD) and one class of drugs (Schedule II controlled substances). There is a finite number of drugs for which DHS had to provide information. The same is true of last session's new s. 50.08. In the case of this draft, we are dealing with all drugs and any off-label uses (of which there may be countless for certain drugs). Is DHS just supposed to describe the concept of "off-label" or is it supposed to create an information sheet for every off-label use of every drug? If it is the latter, I'm not sure that's even possible.

Do you want to provide for someone other than the patient signing the attestation in the case of incapacity of the patient? Do you want there to be an exception for emergencies?

I haven't looked in-depth at the conflict of interest provision yet, but I thought I would get these questions out first. If you want me to pose these questions directly to Rep. Krusick's office, please let me know.

I will be out of the office tomorrow, October 14, so there's no rush to get back to me on these questions.

Tami

**Tamara J. Dodge**
Attorney
Wisconsin Legislative Reference Bureau
P.O. Box 2037
Madison, WI 53701-2037
(608) 267 - 7380
tamara.dodge@legis.wisconsin.gov

---

**From:** Matthias, Mary
**Sent:** Monday, October 03, 2011 11:37 AM
**To:** Dodge, Tamara
**Cc:** Johnson, Rachel
**Subject:** drafting request-medical practice

Good morning-

I am not sure if you're the correct person for this draft- if not, could you forward it to the correct drafter? Thanks.

Rep. Krusick would like a draft requiring prescribers to notify patients about "off-label" uses of drugs and medical devices AND to inform patients about any financial interest a physician may have in a drug or device they prescribe or use.

According to Wikipedia: **Off-label use** is the practice of prescribing pharmaceuticals for an unapproved indication or in an unapproved age group, unapproved dose or unapproved form of administration

It isn't necessary to use the term "off-label" anywhere in the draft.

The draft should provide all of the following:

1. If a physician (or other prescriber) prescribes a drug for an "off-label" use, the prescriber must notify the patient that the prescribed use is "off-label" and obtain the patient's signature attesting that they have received the information. This can be a one-time notification (provided the first time the prescriber prescribes the drug for a particular patient). The doctor should maintain the record—do you have nay thoughts on what would be a reasonable amount of time for maintenance of the record?

2. If a physician intends to use a device or drug in the course of treating a patient (such as installing a device in a patient's body or using a drug during surgery) and the use of the device or drug is "off-label", the physician must provide written information explaining that the use is "off-label" and what that means, and must obtain the patient's signature attesting that they have received the information.

3. Require DHS to prepare the written information that prescribers must hand out to patients for items 1 and 2 above. The written information must explain what "off-label" use is.

Here's a draft from 2001 that is analogous and might be helpful in drafting items 1-3 (there are extraneous things in the 2001 draft that Rep. Krusick doesn't need in this draft, such as explanation of alternatives, statement about military service, etc.)

https://docs.legis.wisconsin.gov/2001/related/proposals/ab672.pdf

4. Require a physician to disclose to a patient if the prescriber has any conflict of interest in a drug, device or other product they are prescribing to a patient or intend to use in treating the patient that is not directly prescribed to the patient (such as a device or drug used during surgery). I don't think you necessarily have to use the term conflict of interest. The general idea is that if the physician has any sort of financial interest in the drug or device-or the company producing the drug or device- or is going to get a kickback--anything other that what is "usual and customary" for a physician to receive for prescribing or using a drug or device—then they have to inform the patient of the nature of the relationship that they have with the company. Require the physician to obtain and maintain written verification that they have made the disclosure to the patient.

Thanks--

Mary

*Mary Matthias*
Senior Staff Attorney
Wisconsin Legislative Council Staff
Ph.(608)266-0932;Fax (608)266-3830

**Dodge, Tamara**

**From:** Matthias, Mary
**Sent:** Thursday, November 10, 2011 11:30 AM
**To:** Dodge, Tamara
**Subject:** RE: drafting request-medical practice

Tami-

Sorry I did not respond to your earlier e-mail.

I think keeping the attestation in the medical record, and not having to specify a separate period of retention, is a good idea.

A one-time disclosure that a prescribed use of a particular drug is "off-label" is enough. If possible, I think it would be better NOT to tie this disclosure in as part of "informed consent". (It should be a freestanding requirement.)

The DHS informational sheet should just describe the concept of off-label use-no need to prepare specific info sheets for different drugs.

Yes to both the emergency exemption and requiring/allowing someone else to sign on behalf of incapacitated patient.

Thanks!

*Mary Matthias*
Senior Staff Attorney
Wisconsin Legislative Council Staff
Ph.(608)266-0932;Fax (608)266-3830

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**From:** Dodge, Tamara
**Sent:** Thursday, November 10, 2011 10:31 AM
**To:** Matthias, Mary
**Subject:** FW: drafting request-medical practice

Mary,

I just wanted to make sure you received these questions below regarding the draft request from Representative Krusick. I am awaiting answers to the questions before starting the draft.

If you would like to discuss my questions, please contact me. Again, if you would like me to contact Rep. Krusick's office directly, I will do that.

Thanks,
Tami

**Tamara J. Dodge**
Attorney
Wisconsin Legislative Reference Bureau

P.O. Box 2037
Madison, WI 53701-2037
(608) 267 - 7380
tamara.dodge@legis.wisconsin.gov

---

**From:** Dodge, Tamara
**Sent:** Thursday, October 13, 2011 4:39 PM
**To:** Matthias, Mary
**Cc:** Johnson, Rachel
**Subject:** RE: drafting request-medical practice

Mary,

I'm have some questions about this drafting request.

First, to answer your question: The signed attestation about receiving information about off-label use should probably be included in the patient's medical record and then the time for keeping that would be tied to the time the medical record is maintained. If you are referring to the time the attestation should be renewed for the same use of the same drug, last year's psychotropic drug section (s. 50.08) provides that the consent is valid for not longer than 15 months. The ADHD draft uses 2 years. Either of those seem reasonable.

What exactly is DHS supposed to create with regard to off-label use? In the example draft, DHS could create information sheets because it was dealing with one disorder (ADHD) and one class of drugs (Schedule II controlled substances). There is a finite number of drugs for which DHS had to provide information. The same is true of last session's new s. 50.08. In the case of this draft, we are dealing with all drugs and any off-label uses (of which there may be countless for certain drugs). Is DHS just supposed to describe the concept of "off-label" or is it supposed to create an information sheet for every off-label use of every drug? If it is the latter, I'm not sure that's even possible.

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Tami

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**Cc:** Johnson, Rachel
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Thanks--

Mary

*Mary Matthias*
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4. Require a physician to disclose to a patient if the prescriber has any conflict of interest in a drug, device or other product they are prescribing to a patient or intend to use in treating the patient that is not directly prescribed to the patient (such as a device or drug used during surgery). I don't think you necessarily have to use the term conflict of interest. The general idea is that if the physician has any sort of financial interest in the drug or device-or the company producing the drug or device- or is going to get a kickback--anything other that what is "usual and customary" for a physician to receive for prescribing or using a drug or device—then they have to inform the patient of the nature of the relationship that they have with the company. Require the physician to obtain and maintain written verification that they have made the disclosure to the patient.

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# RIN Data

**DOD/DODOASHA** **RIN:** 0720-AB23 **Publication ID:** Spring 2011

**Title:** TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

**Abstract:** This rule revises the definition of "unlabeled or off-label drug" to "off-label use of a drug or device." This revision is consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq). Additionally, this rule removes the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed under section 199.4(g)(15). As it is determined that reliable evidence demonstrates that previously unproven drugs, devices, and medical treatments or procedures have proven medical effectiveness, TRICARE has removed them from the list and authorized medically necessary care. This removal of the partial list is necessary as the list will never be completely current and is only a partial list of examples. The removal of this partial list does not change or eliminate any benefits that are currently available under the TRICARE program.

**Agency:** Department of Defense(DOD)

**Priority:** Substantive, Nonsignificant

**RIN Status:** Previously published in the Unified Agenda

**Agenda Stage of Rulemaking:** Final Rule Stage

**Major:** No

**Unfunded Mandates:** No

**CFR Citation:** 32 CFR 199

**Legal Authority:** 5 USC 301; 10 USC ch 55

**Legal Deadline:** None

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 08/10/2004 | 69 FR 48433 |
| NPRM Comment Period End | 10/12/2004 | |
| Second NPRM | 08/31/2009 | 74 FR 44797 |
| Second NPRM Comment Period End | 10/30/2009 | |
| Final Action | 06/00/2011 | |

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Federalism:** No

**Included in the Regulatory Plan:** No

**RIN Data Printed in the FR:** No

**Related RINs:** Previously reported as 0720-AA88

**Agency Contact:**

Rene Morrell
Department of Defense
Office of Assistant Secretary for Health Affairs
1200 Defense Pentagon,
Washington, DC 20301
Phone:303 676-3618

## The Federal Register

## The Daily Journal of the United States Government

Proposed Rule

# TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

A Proposed Rule by the **Defense Department** on **08/31/2009**

## Summary

The Department of Defense is publishing this proposed rule to revise the definition of "unlabeled or off-label drug" to "off-label use of a drug or device." This revision is consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act. Additionally, this rule removes the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed in TRICARE regulations. As it is determined that reliable evidence demonstrates that previously unproven drugs, devices, and medical treatments or procedures have proven medical effectiveness, TRICARE has removed them from the list and authorized medically necessary care. This revision removing the partial list is necessary as the list will never be completely current, and is only a partial list of examples. The removal of this partial list does not change or eliminate any benefits that are currently available under the TRICARE program.

# Table of Contents



# DATES:

Written comments received at the address indicated below by October 30, 2009 will be accepted.

# ADDRESSES:

You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by either of the following methods:

- Federal Rulemaking Portal: **http://www.regulations.gov**. Follow the instructions for submitting comments.
- Mail: Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301-1160.

Instructions: All submissions received must include the agency name and docket number or RIN for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at **http://www.regulations.gov** as they are received without change, including any personal identifiers or contact information.

# FOR FURTHER INFORMATION CONTACT:

René L. Morrell, TRICARE Management Activity, Medical Benefits and Reimbursement Branch, telephone (303) 676-3618.

# SUPPLEMENTARY INFORMATION:

This proposed rule revises the definition of "unlabeled or off-label drug" to "off-label use of a drug or device." This revision is consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Additionally, this proposed rule removes the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed under § 199.4(g)(15).

## Off-Label Uses of Devices

On January 6, 1997, the Office of the Secretary of Defense published a final rule in the Federal Register (62 FR 627-631) clarifying the TRICARE exclusion of unproven drugs, devices, and medical treatments or procedures and adding the TRICARE definition of unlabeled or off-label drugs. This rule also added the provision for coverage of unlabeled or off-label uses of drugs that are Food and Drug Administration (FDA) approved drugs that are prescribed or administered by a health care practitioner and are used for indications or treatments not included in the approved labeling. We are now modifying the definition of "unlabeled or off-label drug" to "off-label use of a drug or device" to be consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) However, this proposed rule does not present new agency policy. Rather, it corrects an error and omission from the current rule. Coverage is limited to those indications for which there is reliable evidence, as defined in section 199.2, sufficient to establish that the off-label use is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. In addition, the off-label use must be reviewed for medical necessity.

## Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

By law, TRICARE can only cost-share medically necessary supplies and services. Any drug, device, and medical treatment or procedure, the safety and efficacy of which have not been established, as described in § 199.4(g)(15), is unproven and cannot be cost-shared by TRICARE except as authorized under § 199.4(e)(26). The current regulation and program policy provide a partial list of examples of unproven drugs, devices, and medical treatments or procedures that are excluded from benefits. The intent of this partial list was to provide information on specific examples of emerging

drugs, devices, and medical treatments or procedures determined to be unproven by TRICARE based on review of current reliable evidence. Due to the rapid and extensive changes in medical technology it is not feasible to maintain this list in the regulation. Removal of this partial list of examples does not change the exclusion of unproven drugs, devices, and medical treatments or procedures. Removal of the partial list of examples does not change the process TRICARE follows in determining for purposes of benefit coverage when a drug, device, and medical treatment or procedure has moved from the status of unproven to proven medical effectiveness. The intent of this revision is to ensure that benefit determinations are made based on current reliable evidence rather than relying on outdated regulatory and policy provisions.

# Regulatory Procedures

## Executive Order 12866, "Regulatory Planning and Review"

Section 801 of Title 5, U.S.C., and Executive Order (E.O.) 12866 require certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts. It has been certified that this rule is not an economically significant rule, however, it is a regulatory action which has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866.

## Sec. 202, Public Law 104-4, "Unfunded Mandates Reform Act"

It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.

## 96, "Regulatory Flexibility Act" (5 U.S.C. 601)

The Regulatory Flexibility Act (RFA) requires each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This proposed rule will not significantly affect a substantial number of small entities for purposes of the RFA.

## 96, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This rule will not impose significant additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511). Existing information collection requirements of the TRICARE and Medicare programs will be utilized.

## Executive Order 13132, "Federalism"

This proposed rule has been examined for its impact under E.O. 13132 and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government; therefore, consultation with State and local officials is not required.

## List of Subjects in 32 CFR Part 199

Claims, dental health, health care, health insurance, individuals with disabilities, Military personnel.

Accordingly, **32 CFR part 199** is proposed to be amended as follows:

## PART 199—[AMENDED]

1. The authority citation for **32 CFR part 199** continues to read as follows:

## Authority:

**5 U.S.C. 301**; 10 U.S.C. chapter 55.

2. Section 199.2(b) is amended by removing the definition of Unlabeled or Off-Label Drugs and adding a new definition of Off-Label Use of a Drug or Device in alphabetical order to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

* * * * *

Off-Label Use of a Drug or Device. A use other than an intended use for which the drug or device is legally marketed under the Federal Food, Drug, and Cosmetic Act. This includes any use that is not included in the approved labeling for an approved drug or approved device; any use that is not included in the cleared statement of intended use for a device that has been determined by the Food and Drug Administration (FDA) to be substantially equivalent to a legally marketed predicate device and cleared for marketing; and any use of a device for which a manufacturer or distributor would be required to seek pre-market review by the FDA in order to legally include that use in the device's labeling.

* * * * *

3. Section 199.4 is amended by revising the third paragraph of the Note to paragraph (g)(15)(i)(A), and removing paragraph (g)(15)(iv) as follows:

§ 199.4 Basic program benefits.

* * * * *

(g) * * *

(15) * * *

(i) * * *

(A) * * *

## Note:

* * * CHAMPUS will consider coverage of off-label uses of drugs and devices that meet the definition of Off-Label Use of a Drug or Device in Section 199.2(b). Approval for reimbursement of off-label uses requires review for medical necessity, and also requires demonstrations from reliable evidence, as defined in § 199.2, that the off-label use of the drug or device is safe, effective and in accordance with nationally accepted standards of practice in the medical community.

* * * * *

Dated: August 21, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E9-20683 Filed 8-28-09; 8:45 am]

BILLING CODE 5001-06-P

**Site Feedback**

TODAY OR TOMORROW, IF possible

# State of Wisconsin
## 2011 - 2012 LEGISLATURE

In 12-9-11

LRB-3064/P1
FFK:.....

sac tcjs

## PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

gen cat

AN ACT ...; **relating to:** the prescription and use of drugs and devices.

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***Analysis by the Legislative Reference Bureau***

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

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***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

**SECTION 1.** 146.88 of the statutes is created to read:

CS

**146.88 Off-label use of a drug or device. (1)** Definitions. In this section and s. 146.885:

(a) "Device" has the meaning given in 450.01 (6).

5. e

21 USC 321(h)

****NOTE: This definition is from the pharmacy examining board chapter. Please let me know if this is inconsistent with your intent.

ins 1-5

(d) (b) "Off-label use" means a use that is not an intended use for which a drug or device is legally marketed under the federal Food, Drug, and Cosmetic Act, 21 USC 301 to 399a. "Off-label use" includes any use that is not included in the approved

labeling for an approved drug or an approved device, any use that is not included in the cleared statement of intended use for a device that has been determined by the federal food and drug administration to be substantially equivalent to a legally marketed predicate device and cleared for marketing, and any use of a device for which the manufacturer or distributor would be required to seek pre-market review by the federal food and drug administration in order to legally include that use in the device's labeling.

****NOTE: I copied this definition from a proposed federal rule (currently in the final rule stage) that describes off-label use for the purpose of military health insurance coverage. The federal Department of Defense published the proposed rule to revise this definition to be consistent with the regulatory framework of the Food, Drug, and Cosmetic Act. Please let me know if this definition is inconsistent with your intent.

Ins 2-7

(f) (c) "Practitioner" has the meaning given in s. 450.01 (17).

****NOTE: This is the definition from the pharmacy examining board chapter. It means "a person licensed in this state to prescribe and administer drugs or licensed in another state and recognized by this state as a person authorized to prescribe and administer drugs." Please confirm that this definition covers who you described as a "physician (or other prescriber)."

**(2)** INFORMATIONAL MATERIALS. (a) The department shall prepare informational materials that provide an explanation of off-label use and an explanation of uses that may be legally marketed under the federal Food, Drug, and Cosmetic Act, 21 USC 301 to 399a.

****NOTE: This paragraph requires the information materials to explain uses that may be legally marketed under the Food, Drug, and Cosmetic Act for purposes of comparison. Please let me know if this is inconsistent with your intent.

(b) The department shall make the materials prepared under par. (a) shall be made available to practitioners and to the public on the department's internet site. Upon the request of a practitioner, the department shall provide the materials under par. (a) shall be provided to the practitioner in printed form.

(c) The materials under par. (a) shall be made available to the public no later than the first day of the 6th month beginning after the effective date of this paragraph.... [LRB inserts date].

****NOTE: This provision is from the bill you provided as a sample. Please let me know if 6 months is not an appropriate time frame for this bill.

(d) The department shall periodically review the materials under par. (a) and shall exercise reasonable diligence in providing materials that are accurate and current.

**(3)** NOTIFICATION FOR OFF-LABEL USE. (a) Except as provided in pars. (c) and (d), a practitioner may not prescribe a drug or device to a patient for an off-label use or use a drug or device in the course of treating a patient in a manner that is an off-label use unless the practitioner does all of the following:

****NOTE: Are there people other than practitioners who may use the drug or device in a manner that is an off-label use that should be included in this prohibition?

1. Informs the patient that the drug or device is being prescribed for or used in a manner that constitutes an off-label use.

2. Provides the patient with the information prepared by the department under sub. (2).

3. Obtains a written certification signed by the patient that states that the patient received the information required under subd. 2. The practitioner shall put the signed written certification in the patient's medical record.

(b) If a patient is incapacitated, a practitioner may provide the information required under par. (a) to a person acting on behalf of the patient and the person acting on behalf of the patient may sign the written certification that is required under par. (a) 3.

(c) A practitioner may prescribe a drug or device to a patient for an off-label use or use a drug or device in the course of treating a patient in a manner that is an off-label use if there is a written certification in the patient's medical record related to the drug or device that was signed no more than 2 years before the date of the proposed prescription or use.

****NOTE: This ties the certification to specific drug or device rather than to the off-label use. This means that a practitioner does not have to do another disclosure to prescribe or use a drug or device for a new off-label use. Is this consistent with your intent?

(d) A practitioner may prescribe a drug or device to a patient for an off-label use or use a drug or device in the course of treating a patient in a manner that is an off-label use in an emergency.

****NOTE: There is currently no express penalty provision included in this draft. This means that the general default penalty for statutes without an express penalty applies, which is a $200 forfeiture. Please let me know if this is consistent with your intent. You may also wish to consider whether a violation of this section should be considered unprofessional conduct for purposes of licensing under ch. 448.

**SECTION 2.** 146.885 of the statutes is created to read:

**146.885 Financial interest in drug or device. (1)** (a) Except as provided in sub. (2), before prescribing a drug or device to a patient or using a drug or device in the course of treating a patient, a practitioner shall disclose to the patient, or if the patient is incapacitated, a person acting on behalf of the patient, any financial interest the practitioner has in the drug or device, including any financial interest the practitioner has in the company that produces or markets the drug or device. A financial interest in a drug or device includes the receipt of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, in cash or in kind, for prescribing or using the drug or device.

(b) If a practitioner makes a disclosure under par. (a), the practitioner shall obtain a written certification signed by the patient or, if the patient is incapacitated,

***NOTE: Should a financial interest in a drug or device also include a payment for evaluating the drug or device?

a person acting on behalf of the patient, that states that a disclosure was made under this section. The practitioner shall put the signed written certification in the patient's medical record.

****NOTE: As drafted, this requires a written certification only if the practitioner has something to disclose. Additionally, this does not require that the written certification include a description of the financial interest that was disclosed. Is this consistent with your intent?

**(2)** (a) A practitioner may prescribe or use a drug or device without disclosing to the patient the practitioner's financial interest in the drug or device in an emergency.

(b) If a practitioner made a disclosure to a patient related to a specific drug or device within the previous two years, as evidenced by a written certification in the patient's medical record, and the practitioner's financial interest in that specific drug or device has not significantly increased since the written certification was obtained, the practitioner is not required to comply with sub. (1).

****NOTE: Essentially, this means a written certification is good for two years or until the practitioner's financial interest in the drug or device that is being prescribed or used substantially increases. Is this consistent with your intent?

(c) A practitioner is not required to disclose de minimis financial interests that are usual and customary in the medical industry.

****NOTE: It would be useful if you could describe some examples of what you do want to be exempted from the disclosure requirement and what you intend to be disclosed. The definition of what is "usual and customary" in the context of the medical industry (and pharmaceutical marketing) may very well be the type of financial interest that you intend to be disclosed to a patient. For purposes of this draft, I narrowed the exclusion for "usual and customary" financial interests to those that are de minimis in an attempt to require the disclosure of practices that may be usual and customary but may have an impact on a practitioner's use of a drug or device.

**(END)**

**INS 1-5**

(b) "Drug" has the meaning given in 21 USC 321 (g).

(c) "Incapacitated" has the meaning given in s. 50.06 (1).

**END INS 1-5**

**INS 2-7**

(e) "Person acting on behalf of a patient" means a guardian of the person, as defined in s. 54.01 (12), or a health care agent, as defined in s. 155.01 (4).

****NOTE: Please let me know if this definition is not consistent with your intent regarding who may sign a certification on behalf of an incapacitated patient.

**END INS 2-7**

**INS 5-13**

create a.r. Y

create a.r. X

this subsection

**SECTION 1. Initial applicability.**

(1) NOTIFICATION OF OFF-LABEL USE. The treatment of section 146.88 of the statutes first applies to drugs and devices that are used in treating a patient or prescribed to a patient on the effective date of section 146.88 (3) of the statutes.

(2) FINANCIAL INTERESTS. The treatment of section 146.885 of the statutes first applies to drugs and devices that are used in treating a patient or prescribed to a patient on the effective date of this subsection.

LPS: fix component

**SECTION 2. Effective date.** This act takes effect on the day after publication, except as follows:

(1) NOTIFICATION OF OFF-LABEL USE. The creation of section 146.88 (3) of the statutes takes effect on the first day of the 7th month beginning after publication.

****NOTE: This delayed effective date is to accommodate the fact that DHS has up to 6 months to create and distribute the information that a prescriber must provide to a patient before prescribing or using a drug or device for an off-label use.

**END INS 5-13**

use a.r. X

use a.r. Y

and SECTION * (*) of this act

Feb. 9 2012 Meeting w/ Brian Larson (Leg Council)

Move concept to informed consent → ch. 448

① Allow medical board to promulgate rules for off-label uses that do not require specific notification

② Financial disclosures - trigger will be whether the physician is connected to the manufacturer of the drug on the federal database. Fed database is currently being created. [proposed rule status] Need an effective date to take into account when the manufacturer will start reporting. Allow 6 months after the database is up & running.

* ~~sunset~~ sunset 1/1/2015, if database not in effect

③ ~~No written~~ No informational materials from DHS

④ No written documentation in the file

⑤ ~~Affect~~ Intent of these changes - simplifies process regarding notification by ~~increasing~~ using existing informed consent process. This draft will now ~~also~~ provide specific information that must be given as part of the informed consent process when a person is prescribing or using an off-label drug or device



*** Current through PL 112-90, approved 1/3/12 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 7. SOCIAL SECURITY ACT
TITLE XI. GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION
PART A. GENERAL PROVISIONS

**Go to the United States Code Service Archive Directory**

*42 USCS § 1320a-7h*

§ 1320a-7h. Transparency reports and reporting of physician ownership or investment interests

(a) Transparency reports.

(1) Payments or other transfers of value.

(A) In general. On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

(i) The name of the covered recipient.

(ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.

(iii) The amount of the payment or other transfer of value.

(iv) The dates on which the payment or other transfer of value was provided to the covered recipient.

(v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as--

(I) cash or a cash equivalent;

(II) in-kind items or services;

(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

(IV) any other form of payment or other transfer of value (as defined by the Secretary).

(vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as--

(I) consulting fees;

(II) compensation for services other than consulting;

(III) honoraria;

(IV) gift;

(V) entertainment;

(VI) food;

(VII) travel (including the specified destinations);

(VIII) education;

(IX) research;

(X) charitable contribution;

(XI) royalty or license;

(XII) current or prospective ownership or investment interest;

(XIII) direct compensation for serving as faculty or as a speaker for a medical education program;

(XIV) grant; or

(XV) any other nature of the payment or other transfer of value (as defined by the Secretary).

(vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.

(viii) Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

(B) Special rule for certain payments or other transfers of value. In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

(2) Physician ownership. In addition to the requirement under paragraph (1)(A), on March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c) [*42 USCS § 1395nn*]) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a) [*42 USCS § 1395nn(a)*])) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

(A) The dollar amount invested by each physician holding such an ownership or investment interest.

(B) The value and terms of each such ownership or investment interest.

(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (viii) of paragraph (1)(A), except that in applying such clauses, "physician" shall be substituted for "covered recipient" each place it appears.

(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.

(b) Penalties for noncompliance.

(1) Failure to report.

(A) In general. Subject to subparagraph (B) except as provided in paragraph (2), any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $ 1,000, but not more than $ 10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A [*42 USCS § 1320a-7a*] are imposed and collected under that section.

(B) Limitation. The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $ 150,000.

(2) Knowing failure to report.

(A) In general. Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $ 10,000, but not more than $ 100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A [*42 USCS § 1320a-7a*] are imposed and collected under that section.

(B) Limitation. The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $ 1,000,000.

(3) Use of funds. Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

(c) Procedures for submission of information and public availability.

(1) In general.

(A) Establishment. Not later than October 1, 2011, the Secretary shall establish procedures--

(i) for applicable manufacturers and applicable group purchasing organizations to submit information to the Secretary under subsection (a); and

(ii) for the Secretary to make such information submitted available to the public.

(B) Definition of terms. The procedures established under subparagraph (A) shall provide for the definition of terms (other than those terms defined in subsection (e)), as appropriate, for purposes of this section.

(C) Public availability. Except as provided in subparagraph (E), the procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that--

(i) is searchable and is in a format that is clear and understandable;

(ii) contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply, as applicable;

(iii) contains information that is able to be easily aggregated and downloaded;

(iv) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year;

(v) contains background information on industry-physician relationships;

(vi) in the case of information submitted with respect to a payment or other transfer of value described in subparagraph (E)(i), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;

(vii) contains any other information the Secretary determines would be helpful to the average consumer;

(viii) does not contain the National Provider Identifier of the covered recipient, and

(ix) subject to subparagraph (D), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

(D) Clarification of time period for review and corrections. In no case may the 45-day period for review and submission of corrections to information under subparagraph (C)(ix) prevent such information from being made available to the public in accordance with the dates described in the matter preceding clause (i) in subparagraph (C).

(E) Delayed publication for payments made pursuant to product research or development agreements and clinical investigations.

(i) In general. In the case of information submitted under subsection (a) with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established under subparagraph (A)(ii) shall provide that such information is made available to the public on the first date described in the matter preceding clause (i) in subparagraph (C) after the earlier of the following:

(I) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(II) Four calendar years after the date such payment or other transfer of value was made.

(ii) Confidentiality of information prior to publication. Information described in clause (i) shall be considered confidential and shall not be subject to disclosure under *section 552 of title 5, United States Code*, or any other similar Federal, State, or local law, until on or after the date on which the information is made available to the public under such clause.

(2) Consultation. In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

(d) Annual reports and relation to State laws.

(1) Annual report to Congress. Not later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report that includes the following:

(A) The information submitted under subsection (a) during the preceding year, aggregated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to Congress after the date on which such information is made available to the public under such subsection).

(B) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year.

(2) Annual reports to States. Not later than September 30, 2013 and on June 30 of each calendar year thereafter, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to States after the date on which such information is made available to the public under such subsection).

(3) Relation to State laws.

(A) In general. In the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient (as defined in subsection (e)) on or after January 1, 2012, subject to subparagraph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as so defined) to disclose or report, in any format, the type of information (as described in subsection (a)) regarding such payment or other transfer of value.

(B) No preemption of additional requirements. Subparagraph (A) shall not preempt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information--

(i) not of the type required to be disclosed or reported under this section;

(ii) described in subsection (e)(10)(B), except in the case of information described in clause (i) of such subsection;

(iii) by any person or entity other than an applicable manufacturer (as so defined) or a covered recipient (as defined in subsection (e)); or

(iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

(C) Nothing in subparagraph (A) shall be construed to limit the discovery or admissibility of information described in such subparagraph in a criminal, civil, or administrative proceeding.

(4) Consultation. The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

(e) Definitions. In this section:

(1) Applicable group purchasing organization. The term "applicable group purchasing organization" means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(2) Applicable manufacturer. The term "applicable manufacturer" means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(3) Clinical investigation. The term "clinical investigation" means any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

(4) Covered device. The term "covered device" means any device for which payment is available under title XVIII [*42 USCS §§ 1395* et seq.] or a State plan under title XIX or XXI [*42 USCS §§ 1396* et seq. or *1397aa* et seq.] (or a waiver of such a plan).

(5) Covered drug, device, biological, or medical supply. The term "covered drug, device, biological, or medical supply" means any drug, biological product, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI [*42 USCS §§ 1396* et seq. or *1397aa* et seq.] (or a waiver of such a plan).

(6) Covered recipient.

(A) In general. Except as provided in subparagraph (B), the term "covered recipient" means the following:

(i) A physician.

(ii) A teaching hospital.

(B) Exclusion. Such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

(7) Employee. The term "employee" has the meaning given such term in section 1877(h)(2) [*42 USCS § 1395nn(h)(2)*].

(8) Knowingly. The term "knowingly" has the meaning given such term in *section 3729(b) of title 31, United States Code*.

(9) Manufacturer of a covered drug, device, biological, or medical supply. The term "manufacturer of a covered drug, device, biological, or medical supply" means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

(10) Payment or other transfer of value.

(A) In general. The term "payment or other transfer of value" means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

(B) Exclusions. An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

(i) A transfer of anything the value of which is less than $ 10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $ 100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(ii) Product samples that are not intended to be sold and are intended for patient use.

(iii) Educational materials that directly benefit patients or are intended for patient use.

(iv) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(v) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(vi) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(vii) Discounts (including rebates).

(viii) In-kind items used for the provision of charity care.

(ix) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c) [*42 USCS § 1395nn(c)*]).

(x) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(xi) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.

(xii) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

(11) Physician. The term "physician" has the meaning given that term in section 1861(r) [*42 USCS § 1395x(r)*].

**HISTORY:**

(Aug. 14, 1935, ch 531, Title XI, Part A, § 1128G, as added March 23, 2010, P.L. 111-148, Title VI, Subtitle A, § 6002, 124 Stat. 689.)

# State of Wisconsin
## 2011 – 2012 LEGISLATURE

In 2-23-12

LRB-3064/P1 /P2
FFK:sac&cjs:rs
Stays

## PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

SAV

Redraft

obtaining informed consent for

AN ACT *to create* 146.88 and 146.885 of the statutes; **relating to:** the prescription and use of drugs and devices and granting rule-making authority.

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***Analysis by the Legislative Reference Bureau***

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

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***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

**SECTION 1.** 146.88 of the statutes is created to read:

**146.88 Off-label use of a drug or device. (1)** DEFINITIONS. In this section and s. 146.885:

Ins 1-5

(a) "Device" has the meaning given in 21 USC 321 (h).

(b) "Drug" has the meaning given in 21 USC 321 (g).

(c) "Incapacitated" has the meaning given in s. 50.06 (1).

(c)

(d) "Off-label use" means a use that is not an intended use for which a drug or device is legally marketed under the federal Food, Drug, and Cosmetic Act, 21 USC 301 to 399d.

Ins 2-3

(e) "Person acting on behalf of a patient" means a guardian of the person, as defined in s. 54.01 (12), or a health care agent, as defined in s. 155.01 (4).

****NOTE: Please let me know if this definition is not consistent with your intent regarding who may sign a certification on behalf of an incapacitated patient.

(f) "Practitioner" has the meaning given in s. 450.01 (17).

****NOTE: This is the definition from the pharmacy examining board chapter. It means "a person licensed in this state to prescribe and administer drugs or licensed in another state and recognized by this state as a person authorized to prescribe and administer drugs." Please confirm that this definition covers who you described as a "physician (or other prescriber)."

**(2)** INFORMATIONAL MATERIALS. (a) The department shall prepare informational materials that provide an explanation of off-label use and an explanation of uses that may be legally marketed under the federal Food, Drug, and Cosmetic Act, 21 USC 301 to 399a.

****NOTE: This paragraph requires the information materials to explain uses that may be legally marketed under the Food, Drug, and Cosmetic Act for purposes of comparison. Please let me know if this is inconsistent with your intent.

(b) The department shall make the materials prepared under par. (a) available to practitioners and to the public on the department's Internet site. Upon the request of a practitioner, the department shall provide the materials under par. (a) to the practitioner in printed form.

(c) The department shall make the materials under par. (a) available to practitioners and to the public no later than the first day of the 7th month beginning after the effective date of this paragraph .... [LRB inserts date].

****NOTE: This provision is from the bill you provided as a sample. Please let me know if 6 months is not an appropriate time frame for this bill.

The rest of the draft is deleted (except for "(END)" on page 6)

(d) The department shall periodically review the materials under par. (a) and shall exercise reasonable diligence in providing materials that are accurate and current.

**(3)** NOTIFICATION OF OFF–LABEL USE. (a) Except as provided in pars. (b) to (d), a practitioner may not prescribe a drug or device to a patient for an off–label use or use a drug or device in the course of treating a patient in a manner that is an off–label use unless the practitioner does all of the following:

****NOTE: Are there people other than practitioners who may use the drug or device in a manner that is an off–label use that should be included in this prohibition?

1. Informs the patient that the drug or device is being prescribed for or used in a manner that constitutes an off–label use.

2. Provides the patient with the information prepared by the department under sub. (2).

3. Obtains a written certification signed by the patient that states that the patient received the information required under subds. 1. and 2. The practitioner shall put the signed written certification in the patient's medical record.

(b) If a patient is incapacitated, a practitioner may provide the information required under par. (a) to a person acting on behalf of the patient and the person acting on behalf of the patient may sign the written certification that is required under par. (a) 3.

(c) A practitioner may prescribe a drug or device to a patient for an off–label use or use a drug or device in the course of treating a patient in a manner that is an off–label use if there is a written certification obtained under sub. (3) (a) 3. or (b) in the patient's medical record related to the drug or device that was signed no more than 2 years before the date of the proposed prescription or use.

****NOTE: This ties the certification to the specific drug or device rather than to the off–label use. This means that a practitioner does not have to do another disclosure to prescribe or use a drug or device for a new off–label use. As drafted, a certification signed by a person acting on behalf of an incapacitated patient is effective for 2 years even if the patient ceases to be incapacitated. Is this consistent with your intent?

(d) A practitioner may prescribe a drug or device to a patient for an off–label use or use a drug or device in the course of treating a patient in a manner that is an off–label use in an emergency.

****NOTE: There is currently no express penalty provision included in this draft. This means that the general default penalty for statutes without an express penalty applies, which is a $200 forfeiture. Please let me know if this is consistent with your intent. You may also wish to consider whether a violation of this section should be considered unprofessional conduct for purposes of licensing under ch. 448.

**SECTION 2.** 146.885 of the statutes is created to read:

**146.885 Financial interest in drug or device. (1)** (a) Except as provided in sub. (2), before prescribing a drug or device to a patient or using a drug or device in the course of treating a patient, a practitioner shall disclose to the patient, or if the patient is incapacitated, a person acting on behalf of the patient, any financial interest the practitioner has in the drug or device, including any financial interest the practitioner has in the company that produces or markets the drug or device. A financial interest in a drug or device includes the receipt of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, in cash or in kind, for prescribing or using the drug or device.

****NOTE: Should a financial interest in a drug or device also include a payment for evaluating the drug or device?

(b) If a practitioner makes a disclosure under par. (a), the practitioner shall obtain a written certification signed by the patient or, if the patient is incapacitated, a person acting on behalf of the patient, that states that a disclosure was made under this section. The practitioner shall put the signed written certification in the patient's medical record.

****NOTE: As drafted, this requires a written certification only if the practitioner has something to disclose. Additionally, this does not require that the written certification include a description of the financial interest that was disclosed. Is this consistent with your intent?

**(2)** (a) A practitioner may prescribe or use a drug or device without disclosing to the patient the practitioner's financial interest in the drug or device in an emergency.

(b) If a practitioner made a disclosure to a patient related to a specific drug or device within the previous 2 years, as evidenced by a written certification obtained under sub. (2) (b) in the patient's medical record, and the practitioner's financial interest in that specific drug or device has not significantly increased since the written certification was obtained, the practitioner is not required to comply with sub. (1) when prescribing that specific drug or device to that patient.

****NOTE: Essentially, this means a written certification is good for two years or until the practitioner's financial interest in the drug or device that is being prescribed or used substantially increases. Is this consistent with your intent?

(c) A practitioner is not required to disclose minimal financial interests that are usual and customary in the medical industry.

****NOTE: It would be useful if you could describe some examples of what you do want to be exempted from the disclosure requirement and what you intend to be disclosed. The definition of what is "usual and customary" in the context of the medical industry (and pharmaceutical marketing) may very well be the type of financial interest that you intend to be disclosed to a patient. For purposes of this draft, I narrowed the exclusion for "usual and customary" financial interests to those that are minimal in an attempt to require the disclosure of practices that may be usual and customary but may have an impact on a practitioner's use of a drug or device.

**SECTION 3. Initial applicability.**

(1) NOTIFICATION OF OFF–LABEL USE. The treatment of section 146.88 of the statutes first applies to drugs and devices that are used in treating a patient or prescribed to a patient on the effective date of this subsection.

(2) FINANCIAL INTERESTS. The treatment of section 146.885 of the statutes first applies to drugs and devices that are used in treating a patient or prescribed to a patient on the effective date of this subsection.

**SECTION 4. Effective dates.** This act takes effect on the day after publication, except as follows:

(1) NOTIFICATION OF OFF–LABEL USE. The creation of section 146.88 (3) of the statutes and SECTION 3 (1) of this act take effect on the first day of the 8th month beginning after publication.

****NOTE: This delayed effective date is to accommodate the fact that DHS has up to 6 months to create and distribute the information that a prescriber must provide to a patient before prescribing or using a drug or device for an off–label use.

**(END)**

**INS 1-5**

**SECTION 1.** 448.31 of the statutes is created to read:

**448.31 Informed consent; off-label uses of drugs and devices.** **(1)** In this section:

**END INS 1-5**

**INS. 2-3**

**(2)** (a) Except as provided in par. (b), a physician may not prescribe a drug or device or use a drug or device in the course of treating a patient in a manner that constitutes an off-label use unless the physician first obtains the patient's informed consent. A patient's consent is informed for purposes of this subsection only if all of the following occur:

1. The physician informs the patient that the manner in which the drug or device is being prescribed or used is an off-label use.

2. The physician informs the patient of uses for which the drug or device may be legally marketed under the federal Food, Drug, and cosmetic Act, 21 USC 301-399a.

(b) Paragraph (a) does not apply to an off-label use that the board determines, by rule, is safe and effective.

**SECTION 2.** 448.32 of the statutes is created to read:

**448.32 Informed consent; financial disclosures.** **(1)** In this section, "financial interest" means that the manufacturer of a drug or device provided a payment or other transfer of value to a physician, as described under 42 USC 1320a-7h (a) (1) (A), and information about the payment or transfer of value is available to the public on an internet website under 42 USC 1320a-7h (c) (1) (C).

****NOTE: The federal law applies to payments to covered recipients. Under federal law, a covered recipient is a physician or a teaching hospital. Please let me know if you

want the meaning of "financial interest" to include payments to a teaching hospital at which the physician is either employed or under contract.

**(2)** Beginning on January 1, 2014, no physician may prescribe a drug or device to a patient or use a drug or device in the course of treating a patient if the physician has a financial interest in the drug or device unless the physician first obtains the patient's informed consent. For purposes of this subsection, a patient's consent is informed only if the physician provides the patient with information that is available to the public on an internet website under 42 USC 1320a-7h (c) (1) (C) that is related to any payment or other transfer of value that the manufacturer of the drug or device provided to the physician.

****NOTE: Under federal law, information about payments from manufacturers to physicians must be available to the public on an internet website no later than September 30, 2013.

**SECTION 3.** 448.40 (2) (h) of the statutes is created to read:

448.40 **(2)** (h) Establishing off-label uses that are medically safe and effective.

**END INS. 2-3**

as defined in s. 448.31 (1)(c)

# State of Wisconsin
## 2011 - 2012 LEGISLATURE

LRB-3064/P2
FFK:sac&cjs:jm

**PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION**

AN ACT *to create* 448.31, 448.32 and 448.40 (2) (h) of the statutes; **relating to:** obtaining informed consent for the prescription and use of drugs and devices and granting rule-making authority.

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***Analysis by the Legislative Reference Bureau***

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

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***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

**SECTION 1.** 448.31 of the statutes is created to read:

**448.31 Informed consent; off-label uses of drugs and devices. (1)** In this section:

(a) "Device" has the meaning given in 21 USC 321 (h).

(b) "Drug" has the meaning given in 21 USC 321 (g).

(c) "Off-label use" means a use that is not an intended use for which a drug or device is legally marketed under the federal Food, Drug, and Cosmetic Act, 21 USC 301 to 399d.

**(2)** (a) Except as provided in par. (b), a physician may not prescribe a drug or device or use a drug or device in the course of treating a patient in a manner that constitutes an off-label use unless the physician first obtains the patient's informed consent. A patient's consent is informed for purposes of this subsection only if all of the following occur:

1. The physician informs the patient that the manner in which the drug or device is being prescribed or used is an off-label use.

2. The physician informs the patient of uses for which the drug or device may be legally marketed under the federal Food, Drug, and Cosmetic Act, 21 USC 301-399a.

(b) Paragraph (a) does not apply to an off-label use that the board determines, by rule, is safe and effective.

**SECTION 2.** 448.32 of the statutes is created to read:

**448.32 Informed consent; financial disclosures.** **(1)** In this section, "financial interest" means that the manufacturer of a drug or device provided a payment or other transfer of value to a physician, as described under 42 USC 1320a-7h (a) (1) (A), and information about the payment or transfer of value is available to the public on an Internet Web site under 42 USC 1320a-7h (c) (1) (C).

****NOTE: The federal law applies to payments to covered recipients. Under federal law, a covered recipient is a physician or a teaching hospital. Please let me know if you want the meaning of "financial interest" to include payments to a teaching hospital at which the physician is either employed or under contract.

**(2)** Beginning on January 1, 2014, no physician may prescribe a drug or device to a patient or use a drug or device in the course of treating a patient if the physician

has a financial interest in the drug or device unless the physician first obtains the patient's informed consent. For purposes of this subsection, a patient's consent is informed only if the physician provides the patient with information that is available to the public on an Internet Web site under 42 USC 1320a-7h (c) (1) (C) that is related to any payment or other transfer of value that the manufacturer of the drug or device provided to the physician.

****NOTE: Under ~~federal law~~, information about payments from manufacturers to physicians must be available to the public on an Internet Web site no later than September 30, 2013.

**SECTION 3.** 448.40 (2) (h) of the statutes is created to read:

448.40 **(2)** (h) Establishing off-label uses, as defined in s. 448.31 (1) (c), that are medically safe and effective.

**(END)**

**2011-2012 DRAFTING INSERT**
**FROM THE**
**LEGISLATIVE REFERENCE BUREAU**

## ANALYSIS

Under current law, a physician who treats a patient must inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. A physician who violates this requirement is subject to discipline by the Medical Examining Board (board) for unprofessional conduct and may be fined up to $25,000 and imprisoned for up to 9 months. If the board finds that the physician has engaged in unprofessional conduct, the board may warn or reprimand the physician, or limit, suspend, or revoke any license, certificate, or limited permit granted to the physician.

Under this bill, a physician may not prescribe or use a drug or device in a manner that constitutes an off-label use without obtaining the patient's informed consent unless the board has determined that the off-label use is safe and effective. The bill defines an off-label use as a use that has not been approved by the U.S. Federal Drug Administration (FDA) to be included on the product's label. The bill specifies that a patient's consent is informed only if the physician informs the patient that the drug or device is being prescribed or used in a manner that is an off-label use and of the uses for which the drug or device has been approved by the FDA.

The bill also provides that, beginning on January 1, 2014, a physician may not prescribe or use any drug or device in which the physician has a financial interest unless the physician obtains the patient's informed consent. Under the bill, a physician has a financial interest in a drug or device if the physician has received gifts or payments of more than $10 from the manufacturer of the drug or device and information about that gift or payment is available to the public on an Internet Web site. Under federal law, information on gifts or payments of more than $10 from manufacturers to physicians must be available to the public on an Internet Web site no later than September 30, 2013. The bill specifies that a patient's consent is informed only if the physician provides the patient with any information related to payments the physician received from the manufacturer of a drug or device that is publicly available on the Internet Web site established by the federal government.

Under the bill, a physician who fails to obtain a patient's informed consent related to the off-label use of a drug or device or for the prescription or use of a drug or device in which the physician has a financial interest is subject to the same penalties as a physician who fails to inform a patient about the availability of all alternate, viable medical modes of treatment.

Because this bill creates a new crime or revises a penalty for an existing crime, the Joint Review Committee on Criminal Penalties may be requested to prepare a report concerning the proposed penalty and the costs or savings that are likely to result if the bill is enacted.

**END ANALYSIS**

**SECTION 1.** 448.02 (3) (a) of the statutes is amended to read:

448.02 **(3)** (a) The board shall investigate allegations of unprofessional conduct and negligence in treatment by persons holding a license, certificate or limited permit granted by the board. An allegation that a physician has violated s. 253.10 (3), 448.30, 448.31, 448.32, or 450.13 (2); or has failed to mail or present a medical certification required under s. 69.18 (2) within 21 days after the pronouncement of death of the person who is the subject of the required certificate or ~~that a physician~~ has failed at least 6 times within a 6-month period to mail or present a medical certificate required under s. 69.18 (2) within 6 days after the pronouncement of death of the person who is the subject of the required certificate is an allegation of unprofessional conduct. Information contained in reports filed with the board under s. 49.45 (2) (a) 12r., 50.36 (3) (b), 609.17, or 632.715, or under 42 CFR 1001.2005, shall be investigated by the board. Information contained in a report filed with the board under s. 655.045 (1), as created by 1985 Wisconsin Act 29, which is not a finding of negligence or in a report filed with the board under s. 50.36 (3) (c) may, within the discretion of the board, be used as the basis of an investigation of a person named in the report. The board may require a person holding a license, certificate, or limited permit to undergo, and may consider the results of, one or more physical, mental, or professional competency examinations if the board believes that the results of any such examinations may be useful to the board in conducting its investigation.

**History:** 1975 c. 383, 421; 1977 c. 418; 1981 c. 135, 375, 391; 1983 a. 188 s. 10; 1983 a. 189 s. 329 (5); 1983 a. 253, 538; 1985 a. 29; 1985 a. 146 s. 8; 1985 a. 315, 332, 340; 1987 a. 27, 399, 403; 1989 a. 229; 1991 a. 186; 1993 a. 105, 107; 1995 a. 309; 1997 a. 67, 175, 191, 311; 1999 a. 32, 180; 2001 a. 89; 2009 a. 382.

**END INS. 1-4**

**Basford, Sarah**

**From:** Krusick, Peggy
**Sent:** Friday, March 09, 2012 10:56 AM
**To:** LRB.Legal
**Subject:** Draft Review: LRB 11-3064/1 Topic: Require prescribers to notify about off label use of and financial interest in drugs and medical devices

Dear Legislative Reference Bureau,

Please Jacket LRB 11-3064/1 for the ASSEMBLY.

Thank you for all you do during these very busy days.

Have a great weekend!

Peggy